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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/017,717

12/14/2001

Guy Michael Miller

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7590

05/05/2005

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/017,717	<b>Applicant(s)</b> MILLER ET AL.	
	<b>Examiner</b> Phyllis G. Spivack	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 41,42,44-64 and 98-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41,42,44-64 and 98-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1-27-05</u> . | 6) <input type="checkbox"/> Other: _____  |

Applicants' Request for Continued Examination (RCE) filed January 27, 2005 is acknowledged and accepted. New claims 105 and 106 are presented. Accordingly, claims 41, 42, 44-64 and 98-106 are now under consideration.

An Information Disclosure Statement filed January 27, 2005 is further acknowledged and has been reviewed.

The abstract of the disclosure is objected to because the present claims are not drawn to compositions. Correction is required. See MPEP § 608.01(b).

A new title is noted.

Claims 1-64 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-62 of co-pending application S.N. 10/020450 in the last Office Action due to overlapping subject matter.

Applicants have again elected to hold in abeyance a response to this rejection.

Accordingly, the obviousness-type double patenting rejection is maintained and presently extended to include new claims 105 and 106.

Claims 1-64 and 98 were rejected in the last Office Action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The language of the claims does not preclude other types of tocopherols.

Upon reconsideration, this rejection of record under 35 U.S.C. 112, second paragraph, is withdrawn.

In the last Office Action claims 41-64 and 98 were rejected under 35 U.S.C. 102(e) as being anticipated by Wechter, W.J., US 2004/0058986. It was

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asserted Wechter teaches methods of treating and/or ameliorating the symptoms of a noncardiovascular tissue ischemic condition comprising administering a gamma-tocopherol enriched tocopherol composition or a gamma-tocopherol metabolite enriched composition. Noncardiovascular tissue ischemic conditions include spinal cord ischemia, liver ischemia, kidney ischemia, peripheral nerve damage and neuropathies.

Further, claims 1-64 and 98 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter, W.J., US 2004/0058986. It was asserted Wechter broadly claims methods of treating or preventing any ischemic condition comprising administering a composition comprising tocopherols, at least 50% of which being gamma-tocopherol, as well as a metabolite (LLU-I) of gamma-tocopherol. Claimed ischemic conditions include those associated with the liver, the kidney, diabetes, thromboembolic disease, the brain, the nervous system and the eye.

In response to both rejections, Applicants again argue there is no support in the specification for the claims as filed in Wechter, W.J., US 2004/0058986, now allowed, for methods of treating and/or ameliorating symptoms of a non-cardiovascular tissue ischemic condition by administering a gamma-tocopherol enriched tocopherol composition comprising at least 50% gamma-tocopherol or a naturally occurring metabolite of gamma-tocopherol. Applicants urge the claimed subject matter in the references may not benefit from the earlier filing dates.

Applicants' arguments have been given careful consideration by a panel of two supervisory examiners, one an interference specialist, and the examiner for Wechter,

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W.J., US 2004/0058986. It was determined an interference will not be declared between the pending applications because there is a difference of more than three months in the effective filing dates of the oldest and the next oldest applications, in the case of inventions of a simple character, or a difference of more than six months in the effective filing dates of the applications in other cases, except in exceptional situations, as determined and approved by the TC Director. See 37 CFR 1.603.

Accordingly, the rejection of claims 41, 42 and 44-64 under 35 U.S.C. 102(e) as being anticipated by Wechter, W.J., US 2004/0058986 and the rejection of claims 41, 42, 44-64 and 98 under 35 U.S.C. 103(a) as being unpatentable over Wechter, W.J., US 2004/0058986, as set forth *supra*, are maintained and presently extended to include claims 99-106.

Claims 41, 44-52, 58-64 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilenko et al., Byulleten' Eksperimental'noi Biologii i Meditsiny (abstract). It was asserted Bilenko teaches the administration of alpha-tocopherol in a method of preventing lesions associated with a non-cardiovascular tissue ischemic condition. A lesion may be defined as diseased tissue. Claim 41 employs open language that permits the administration of non-gamma tocopherols in the claimed method of reducing tissue death associated with non-cardiovascular tissue ischemia.

Applicants argue there is no teaching or suggestion in Bilenko that would motivate one of skill in the art to administer a gamma tocopherol enriched composition

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comprising 50% gamma tocopherol to reduce cell or tissue death associated with non-cardiovascular tissue ischemia.

Applicants' arguments are persuasive. This rejection of record is withdrawn.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Mondays to Fridays from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at telephone number 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phyllis G. Spivack  
Primary Examiner  
Art Unit 1614

**PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**

April 30, 2005